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JEFFER, MANGELS, BUTLER & MARMARO LLP
A LIMITED LIABILITY PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

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Official Fax

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Date: January 31, 2002

From: Kathy Mojibi, Esq.

Deliver to: Examiner Al Robinson, Art Unit 1616

Facsimile: (703) 746-4998 Telephone: (703) 308-4524

Serial #: 09/706,158 Filed: November 3, 2000
Docket #: 57974-5004 Client Name: Tor McPartland

Total number of pages (including this page): ²⁹~~28~~ If you do not receive this number of pages,
please contact our FAX operator at (310) 203-8080 ext. 6626.

Dear Examiner Robinson:

As you requested, enclosed is a copy of the declaration that was originally filed with the preliminary amendment on December 20, 2000. A copy of the returned postcard stamped by the Office indicating receipt of the declaration is enclosed.

You have advised us that the Office Action will be reissued. Accordingly, we will not respond to the Action issued on December 21, 2001.

If you have any questions, do not hesitate to contact us.

Regards, Kathy Mojibi

A HARD COPY OF THE DOCUMENT(S) WILL NOT BE SENT

This FAX is intended only for the use of the individual or entity to which it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the intended recipient, any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original FAX to us at the above address by the US Postal Service. Thank you.

LADOC52623839 1

PATENT	
Serial/Patent No. <u>09706,158</u>	File No. <u>57974-5004</u> Date Mailed <u>12-20-00</u> By: <u>LR4/Kxm</u>
Title: <u>Ant Spray Containing D-Limonene and Methods of Making and using Same</u>	
Client Name: <u>Tor McPartland</u>	
The Following, due _____ in the U.S. Patent and Trademark Office, was received in the Patent and Trademark Office on the date stamped hereon:	
<input checked="" type="checkbox"/> Amendment/Response <input type="checkbox"/> Application for Patent including <u> </u> Pages of Spec.: No. of Claims <u> </u> <input type="checkbox"/> Drawings: # of Sheets <u> </u> <u> </u> Formal <u> </u> Informal <input checked="" type="checkbox"/> Declaration, Affidavit or Oath, Power of Attorney <input type="checkbox"/> Assignment w/PTO Form 1595 <input type="checkbox"/> Verified Statement <input type="checkbox"/> Form 1082 - New Appln. Transmittal (duplicate) <input type="checkbox"/> Petition for Extension of Time <input type="checkbox"/> Check No. _____ for \$ _____ <input type="checkbox"/> Check No. _____ for \$ _____ <input type="checkbox"/> Check No. _____ for \$ _____	<input type="checkbox"/> Transmittal Letter <input type="checkbox"/> Issue Fee Transmittal (duplicate) <input type="checkbox"/> Maintenance Fee Transmittal <input type="checkbox"/> Letter Re <input type="checkbox"/> Notice of Appeal <input type="checkbox"/> Priority: _____ of Docs <input type="checkbox"/> Certified Copy: # _____ of Docs <input type="checkbox"/> Information Disclosure Statement w/ _____ cited references <input checked="" type="checkbox"/> Express Mail No. <u>EL58466847545</u> <input type="checkbox"/> Certificate of Mailing <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____

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PATENT & TRADEMARK OFFICE

CALENDARED

JAN 25 2001

Jeffer, Mangels, Butler & Marmaro LLP

By:

PATENT
57974-5004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Tor MCPARTLAND

Serial No. 09/706,158

Filed: November 3, 2000

For: ANT SPRAY CONTAINING D-
LIMONENE AND METHODS OF
MAKING AND USING SAME

Group Art Unit: 1617

Examiner: ROBINSON, A.

PRELIMINARY AMENDMENT

Applicant hereby submits the declaration of Tor McPartland, previously submitted in the parent application, to be considered in view of the claims of this continuation-in-part application. The declaration is submitted as evidence of novelty and non-obviousness.

The acceptance by the Organic Material Review Institute ("OMRI") of Applicant's product for use in organic production was significant for several reasons. First, OMRI had to define a new category, "plant extract pesticides," for identification of Applicant's insecticide composition. See Supplemental Declaration of Tor McPartland ("Supp. Decl."), ¶ 7. The fact that OMRI had to

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PATENT
57974-5004

define a new category for Applicant's product evidences the novelty of the product. There were no other plant extract pesticides approved for use in organic production by OMRI prior to Applicant's product. Supp. Decl., ¶ 7.

Second, OMRI's acceptance of Applicant's product was significant in that it boosted the sales of Applicant's product. Supp. Decl., ¶ 8. In 1998, prior to OMRI's acceptance, annual sales of Applicant's product were approximately \$39,000. Supp. Decl., ¶ 8. The following year, upon OMRI's approval, the sales increased six-fold, exceeding \$250,000. Supp. Decl., ¶ 8. The significant increase in sales was not a result of an increase in advertising, as the advertising campaign during 1998 and 1999 remained relatively static. Supp. Decl., ¶ 9. Rather, the commercial success of Applicant's product was a result of Applicant's ability to satisfy a long felt need for an insecticidal composition that is made of food-grade ingredients and can be used in organic production. Supp. Decl., ¶¶ 5, 6, 10 and 11.

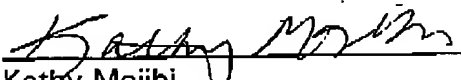
In view of the foregoing remarks, it is believed that all pending claims are in condition for allowance. A Notice of allowance is respectfully requested. Should there be any questions regarding this application, the

PATENT
57974-5004

Examiner is invited to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

December 20, 2000
Date


Kathy Mojibi
Reg. No. 41,409

JEFFER, MANGELS, BUTLER & MARMARO LLP
Tenth Floor
2121 Avenue of the Stars
Los Angeles, CA 90067
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PATENT
57974-5004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Tor McPartland

Serial No. 09/706,158

Filed: November 3, 2000

For: ANT SPRAY CONTAINING D-
LIMONENE AND METHODS OF
MAKING AND USING SAME

Group Art Unit: 1617

Examiner: ROBINSON, A.

CERTIFICATE OF MAILINGThe Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I hereby certify that a Preliminary Amendment; Supplemental Declaration of Tor McPartland; and return postcard are being deposited with the United States Postal Service, postage prepaid, Express Mail No. EL584668475US on the date indicated below and addressed to: The Assistant Commissioner for Patents, Washington, D.C. 20231.

December 20, 2000

(Date of Deposit)

Laurie A. Rossi

(Name of Person Mailing Paper or Fee)

Laurie A. Rossi

(Signature)

PATENT
57974-5002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Tor McPartland

Serial No. 09/218,732

Filed: December 22, 1998

For: ANT SPRAY CONTAINING D-
LIMONENE AND METHODS OF
MAKING AND USING SAME

Group Art Unit: 1614

Examiner: A. Robinson

SUPPLEMENTAL DECLARATION OF TOR MCPARTLANDUNDER 37 C.F.R. § 1.132

I, Tor McPartland, declare that:

1. I am the inventor of the subject matter of all claims of the above-captioned United States patent application.
2. I am President of Orange Guard, Inc., which manufactures and markets the composition claimed in the captioned application under the mark Orange Guard®.

Serial No. 09/218,732

3. I have a thorough knowledge of the composition of Orange Guard®, as well as the sales and marketing of the product. More specifically, I have a thorough knowledge of the customer base of my company.

4. I make this Declaration in response to the rejection for obviousness in the Office Actions mailed September 14, 1999 and May 3, 2000, to show that Orange Guard® is a commercial success, and the reasons therefor.

5. Orange Guard® is successful because it safe. In fact, each of the ingredients used in Orange Guard® may be used as food additive. The ingredients are included in the current list of compounds Generally Recognized as Safe by the United States Food and Drug Administration. 21 C.F.R. §§ 170.30 182.1, 182.6 and 172.510. Copies attached as Exhibit A hereto.

6. More importantly, Orange Guard® is the only insecticide that is allowed for use in organic food production. Attached hereto as Exhibit B is a letter from the Organic Materials Review Institute ("OMRI") dated June 1, 1999 granting me the right to label Orange Guard® as allowed for use in organic production. OMRI is a private entity that reviews and lists products that may be labeled as allowed for use in organic food production and agriculture.

Serial No. 09/218,732

7. When OMRI approved Orange Guard® for use in organic food production, it had to create a new category, entitled "plant extract pesticides," to identify Orange Guard®. Prior to the approval of Orange Guard®, there had been no other plant extract pesticides approved by OMRI. Orange Guard® is the only organic pesticide that is a plant extract listed by OMRI.

8. The commercial success of Orange Guard® was generally as a result of its ingredients which were approved by OMRI. Orange Guard® was first offered for sale in November, 1997. Sales of the product were negligible. The first significant sales occurred in May, 1998. Total sales of Orange Guard® for 1998 were approximately \$39,000. In 1999, when OMRI allowed use of Orange Guard® in organic production, sales exceeded \$250,000. Current estimates are for sales of about \$650,000 in 2000. If, as I expect, Orange Guard® is allowed for use in organic agriculture, sales for 2000 are projected to be about \$2,000,000.

9. The significant increase in the success of Orange Guard® is not a result of an aggressive advertising campaign but a result of the recognition by a reputable organization, such as OMRI, of the safe, food-grade ingredients of Orange Guard®. The OMRI listing tells the public that all the ingredients are plant extracts that meet OMRI's strict

Serial No. 09/218,732

requirements for use in organic production. This is the assurance the public wants before they use an insecticide. Our customers are our best advertising and salesman. Without OMRI, they would not take our word for the inert ingredients safety. With our QVC exposure (sales not paid advertising), paid advertising has not been a big help for us, but when we get a mention (unsolicited) in an environmental magazine or newspaper column, the response is incredible. When a magazine or columnist that the public knows and trusts endorses or just mentions Orange Guard®, their readers become apostles for Orange Guard®. People are finding out about our product and its safety. The last time I was on QVC a lady called and suggested I get the Nobel Prize for peace because of the safety and efficacy of Orange Guard®. People with allergies and chemical sensitivities can use Orange Guard without problems. In fact, the advertising expenditure of Orange Guard® has not varied significantly from year to year. In 1998, a total of about \$5,000 was spent on advertising. In 1999, about \$13,000 was spent on advertising and in 2000, the forecasted budget for advertising is about \$10,000.

10. Attached as Exhibit C to my declaration are true and correct copies of three (3) emails and a letter I received attesting to the fact that the inventive product has solved a long-felt but unsolved need.

11. To my knowledge, there are no other pesticides that are allowed for use in organic food production or organic agriculture. The market for organic food has created a strong demand for Orange Guard that no other product satisfies.

10-03-200 12:18PM

FROM ORANGE GUARD. INC. 8316595128

P. 1

008

Serial No. 09/218.732

12. I have been interested and involved in organic food and its production for the past twenty years. I have an organic vineyard and am a consumer of organic foods.

13. A person ordinarily skilled in the field would understand from its composition that Orange Guard® could be used in organic food production and organic farming. This is because the active ingredient, and emulsifying agent, D-limonene and castor oil respectively, are both plant extracts. A person skilled in the field would also know that the only other significant ingredients, water and benzoate of soda, are acceptable for use in organic foods.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent that may issue thereon.

Date

10/3/2000

TOR MCPARTLAND

Tor McPartland

LADOC525599193

21 CFR s 170.30
21 C.F.R. § 170.30

CODE OF FEDERAL REGULATIONS
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN
SERVICES
SUBCHAPTER B--FOOD FOR HUMAN
CONSUMPTION
PART 170--FOOD ADDITIVES
SUBPART B--FOOD ADDITIVE SAFETY
Current through December 7, 1999; 64
FR 68573

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that

use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the use of the substance is safe within the meaning of the act (see § 170.3(i)). Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in this country. Persons claiming GRAS status for a substance based on its common use in food outside of the United States should obtain FDA concurrence that the use of the substance is GRAS.

(d) The food ingredients listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in Part 182, Part 184 or § 186.1 of this chapter.

(e) Food ingredients were listed as GRAS in Part 182 of this chapter during 1958-1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in Part 184 or § 186.1 of this chapter.

(f) The status of the following food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to § 170.35, § 170.38, or § 180.1 of this chapter:

(1) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, and which has been modified by processes first introduced into commercial use after January 1, 1958, which may reasonably be expected significantly to alter the composition of the substance.

(2) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, that has had significant alteration of composition by breeding or selection after January 1, 1958, where the change may be reasonably expected to alter the nutritive value or the concentration of toxic constituents.

(3) Distillates, isolates, extracts, and concentration of extracts of GRAS substances.

(4) Reaction products of GRAS substances.

(5) Substances not of a natural biological origin, including those for which evidence is offered that they are identical to a GRAS counterpart of natural biological origin.

(6) Substances of natural biological origin intended for consumption for other than their nutrient properties.

(g) A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

(h) A food ingredient that is listed as GRAS in Part 182 of this chapter or affirmed as GRAS in Part 184 or § 186.1 of this chapter shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

(1) It complies with any applicable food grade specifications of the Food Chemicals Codex, 2d Ed. (1972), or, if specifically indicated in the GRAS affirmation regulation, the Food Chemicals Codex, 3d

Ed. (1981), which are incorporated by reference, except that any substance used as a component of articles that contact food and affirmed as GRAS in § 186.1 of this chapter shall comply with the specifications therein, or in the absence of such specifications, shall be of a purity suitable for its intended use. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) It performs an appropriate function in the food or food-contact article in which it is used.

(3) It is used at a level no higher than necessary to achieve its intended purpose in that food or, if used as a component of a food-contact article, at a level no higher than necessary to achieve its intended purpose in that article.

(i) If a substance is affirmed as GRAS in Part 184 or § 186.1 of this chapter with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(j) If an ingredient is affirmed as GRAS in Part 184 or § 186.1 of this chapter with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(k) Pursuant to § 170.35, a food ingredient may be affirmed as GRAS in Part 184 or § 186.1 of this chapter for a specific use(s) without a general evaluation of use of the ingredient. In addition to the use(s) specified in the regulation, other uses of such an ingredient may also be GRAS. Any affirmation of GRAS status for a specific use(s), without a general evaluation of use of the ingredient, is subject to reconsideration upon such evaluation.

(l) New information may at any time require

Page 3

21 CFR s 170.30

reconsideration of the GRAS status of a food ingredient. Any change in Part 182, Part 184, or § 186.1 of this chapter shall be accomplished pursuant to § 170.38.

[42 FR 14483, Mar. 15, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 5610, Feb. 14, 1984; 53 FR 16546, May 10, 1988]

< General Materials (GM) - References, Annotations,
or Tables >

21 C. F. R. § 170.30

21 CFR § 170.30

END OF DOCUMENT

21 CFR s 182.1
21 C.F.R. § 182.1

CODE OF FEDERAL REGULATIONS
TITLE 21—FOOD AND DRUGS
CHAPTER I—FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN
SERVICES
SUBCHAPTER E—FOOD FOR HUMAN
CONSUMPTION
PART 182—SUBSTANCES GENERALLY
RECOGNIZED AS SAFE
SUBPART A—GENERAL PROVISIONS
Current through December 7, 1999; 64

FR 68573

§ 182.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and

which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in this part. When the status of a substance has been reevaluated, it will be deleted from this part, and will be issued as a new regulation under the appropriate part, e.g., "affirmed as GRAS" under Part 184 or 186 of this chapter; "food additive regulation" under Parts 170 through 180 of this chapter; "interim food additive regulation" under Part 180 of this chapter; or "prohibited from use in food" under Part 189 of this chapter.

[53 FR 44875, Nov. 7, 1988]

<General Materials (GM) - References, Annotations,
or Tables>

21 C. F. R. § 182.1

21 CFR § 182.1

END OF DOCUMENT

21 CFR s 182.60
21 C.F.R. § 182.60

CODE OF FEDERAL REGULATIONS
TITLE 21—FOOD AND DRUGS
CHAPTER I—FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN
SERVICES

SUBCHAPTER B—FOOD FOR HUMAN
CONSUMPTION

PART 182—SUBSTANCES GENERALLY
RECOGNIZED AS SAFE

SUBPART A—GENERAL PROVISIONS

Current through December 7, 1999; 64

FR 68573

§ 182.60 Synthetic flavoring substances and
adjuvants.

Synthetic flavoring substances and adjuvants that are
generally recognized as safe for their intended use,
within the meaning of section 409 of the act, are as
follows:

Acetaldehyde (ethanal).

Acetoin (acetyl methylcarbinol).

Anethole (parapropenyl anisole).

Benzaldehyde (benzoic aldehyde).

N-Butyric acid (butanoic acid).

d- or l-Carvone (carvol).

Cinnamaldehyde (cinnamic aldehyde).

Citral (2,6-dimethyloctadien-2,6-di-8, geranial, neral).

Decanal (N-decylaldehyde, capraldehyde, capric
aldehyde, caprinaldehyde, aldehyde C-10).

Ethyl acetate.

Ethyl butyrate.

3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-
methyl-phenyl-glycidate, so-called strawberry
aldehyde, C-16 aldehyde).

Ethyl vanillin.

Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-ol).

Geranyl acetate (geraniol acetate).

Limonene (d-, l-, and dl-).

Linalool (linalol, 3,7-dimethyl-1,6-octadien-3-ol).

Linalyl acetate (bergamot).

Methyl anthranilate (methyl-2-aminobenzoate).

Piperonal (3,4-methylenedioxy-benzaldehyde,
heliotropin).

Vanillin.

(Authority: Secs. 201(s), 409, 701(a), 52 Stat. 1055,
72 Stat. 1784-1788 as amended (21 U.S.C. 321(s),
348, 371(a)))

[42 FR 14640, March 15, 1977, as amended at 43 FR
47724, Oct. 17, 1978; 44 FR 3963, Jan. 19, 1979;
44 FR 20656, April 6, 1979; 48 FR 51907, Nov. 15,
1983; 54 FR 7402, Feb. 21, 1989]

<General Materials (GM) - References, Annotations,
or Tables>

21 C. F. R. § 182.60

21 CFR § 182.60

END OF DOCUMENT

21 CFR s 172.510
21 C.F.R. § 172.510

CODE OF FEDERAL REGULATIONS
TITLE 21—FOOD AND DRUGS
CHAPTER I—FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN
SERVICES
SUBCHAPTER B—FOOD FOR HUMAN
CONSUMPTION
PART 172—FOOD ADDITIVES PERMITTED
FOR DIRECT ADDITION TO FOOD FOR
HUMAN
CONSUMPTION
SUBPART F—FLAVORING AGENTS AND
RELATED SUBSTANCES
Current through December 7, 1999; 64

FR 68573

§ 172.510 Natural flavoring substances and natural
substances used in conjunction with flavors.

Natural flavoring substances and natural adjuncts
may be safely used in food in accordance with the
following conditions.

(a) They are used in the minimum quantity required
to produce their intended physical or technical effect
and in accordance with all the principles of good
manufacturing practice.

(b) In the appropriate forms (plant parts, fluids and
solid extracts, concretes, absolutes, oils, gums,
balsams, resins, oleoresins, waxes, and distillates)
they consist of one or more of the following, used
alone or in combination with flavoring substances and
adjuncts generally recognized as safe in food,
previously sanctioned for such use, or regulated in
any section of this part.

Common name	Scientific name	Limitations
Aloe	Aloe pernyi Baker, A. barbadensis Mill., A. ferox Mill., and hybrids of this sp. with A. africana Mill. and A. spicata Baker.	
Althea root and flowers	Althea officinalis L.	
Amyris (West Indian sandalwood)	Amyris balsamifera L.	
Angola weed	Roccella fuciformis Ach	In alcoholic beverages only.
Arnica flowers	Arnica montana L., A. fulgens Pursh, A. sororia Greene, or A. cordifolia Hooker.....	Do.
Artemisia (wormwood)	Artemisia spp	Finished food thujone free. [FN1]
Artichoke leaves	Cynara scolymus L	In alcoholic beverages only.
Benzoin resin	Styrax benzoin Dryander, S. paralleloneurus Perkins, S. tonkinensis (Pierre) Craib ex Hartwich, or other spp. of the Section Anthostyrax of the genus Styrax.	
Blackberry bark	Rubus, Section Eubatus	
Boldus (boldo) leaves ...	Peumus boldus Mol	Do.
Boronia flowers	Boronia megastigma Nees.	
Bryonia root	Bryonia alba L., or B. diocia Jacq ...	Do.
Buchu leaves	Barosma betulina Bartl. et Wendl., B.	

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21 CFR s 172.510

	crenulata (L.) Hook. or B. serratifolia Willd	
Buckbean leaves	Menyanthes trifoliata L	Do.
Cajeput	Melaleuca leucadendron L. and other Melaleuca spp.	
Calumba root	Jateorhiza palmata (Lam.) Miers	Do.
Camphor tree	Cinnamomum camphora (L.) Nees et Eberm	Safrole free.
Cascara sagrada	Rhamnus purshiana DC	
Cassie flowers	Acacia farnesiana (L.) Willd	
Castor oil	Ricinus communis L	
Catechu, black	Acacia catechu Willd	
Cedar, white (aborvitae), leaves and twigs.....	Thuja occidentalis L	Finished food thujone free. [FN1]
Centuary	Centaurium umbellatum Gilib	In alcoholic beverages only.
Cherry pits	Prunus avium L. or P. cerasus L	Not to exceed 25 p.p.m. prussic acid.
Cherry-laurel leaves	Prunus laurocerasus L	Do.
Chestnut leaves	Castanea dentata (Marsh.) Borkh	
Chirata	Swertia chirata Buch.-Ham	In alcoholic beverages only.
Cinchona, red, bark	Cinchona succirubra Pav. or its hybrids	In beverages only; not more than 83 p.p.m. total cinchona alkaloids in finished beverage.
Cinchona, yellow, bark ..	Cinchona ledgeriana Moens, C. calisaya Wedd., or hybrids of these with other spp. of Cinchona	Do.
Copaiba	South American spp. of Copaifera L	
Cork, oak	Quercus suber L., or Q. occidentalis F. Gay	In alcoholic beverages only.
Costmary	Chrysanthemum balsamita L	Do.
Costus root	Saussurea lappa Clarke	
Cubeb	Piper cubeba L. f	
Currant, black, buds and leaves	Ribes nigrum L	
Damiana leaves	Turnera diffusa Willd	
Davana	Artemisia pallens Wall.	

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Dill, Indian	Anethum sowa Roxb. (Peucedanum graveolens Benth et Hook., Anethum graveolens L.).	
Dittany (fraxinella) roots	Dictamnus albus L	Do.
Dittany of Crete	Origanum dictamnus L	
Dragon's blood (dracorubin)	Daemonorops spp	
Elder tree leaves	Sambucus nigra L	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor.
Elecampane rhizome and roots	Inula helenium L	In alcoholic beverages only.
Elemi	Canarium commune L. or C. luzonicum Miq	
Erigeron	Erigeron canadensis L	
Eucalyptus globulus leaves	Eucalyptus globulus Labill	
Fir ("pine") needles and twigs	Abies sibirica Ledeb., A. alba Mill., A. sachalinensis Masters or A. mayriana Miyabe et Kudo.	
Fir, balsam, needles and twigs	Abies balsamea (L.) Mill	
Galanga, greater	Alpinia galanga Willd	Do.
Galbanum	Ferula galbaniflua Boiss. et Buhse and other Ferula spp.	
Gambir (catechu, pale) ..	Uncaria gambir Roxb	
Genet flowers	Spartium junceum L	
Gentian rhizome and roots	Gentiana lutea L	
Gentian, stemless	Gentiana acaulis L	Do.
Germander, chamaedrys ...	Teucrium chamaedrys L	Do.
Germander, golden	Teucrium polium L	Do.
Guaiac	Guaiacum officinale L., G. santum L., Bulnesia sarmienti Lor.	
Guarana	Paullinia cupana HBK	
Haw, black, bark	Viburnum prunifolium L	
Hemlock needles and twigs	Tsuga canadensis (L.) Carr. or T. heterophylla (Raf.) Sarg.	
Hyacinth flowers	Hyacinthus orientalis L	
Iceland moss	Cetraria islandica Ach	Do.
Imperatoria	Peucedanum ostruthium (L.). Koch (Imperatoria ostruthium L.).	
Iva	Achillea moschata Jacq	Do.

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Labdanum	Cistus spp.	
Lemon-verbena	Lippia citriodora HBK	Do.
Linaloe wood	Bursera delpechiana Poiss. and other Bursera spp.	
Linden leaves	Tillia spp.	Do.
Lovage	Levisticum officinale Koch	
Lungmoss (lungwort)	Sticta pulmonacea Ach	
Maidenhair fern	Adiantum capillus-veneris L	Do.
Maple, mountain	Acer spicatum Lam	
Mimosa (black wattle) flowers	Acacia decurrens Willd. var. dealbata.	
Mullein flowers	Verbascum phlomoides L. or V. thapsiforme Schrad.....	Do.
Myrrh	Commiphora molmol Engl., C. abyssinica (Berg) Engl., or other Commiphora spp.	
Myrtle leaves	Myrtus communis L	Do.
Oak, English, wood	Quercus robur L	Do.
Oak, white, chips	Quercus alba L	
Oak moss	Evernia prunastri (L.) Ach., E. furfuracea (L.) Mann, and other lichens.....	Finished food thujone.
Olibanum	Boswellia carteri Birdw. and other Boswellia spp.	
Opopanax (bisabolmyrrh) .	Opopanax chironium Koch (true opopanax) of Commiphora erythraea Engl. var. llabrescens.	
Orris root	Iris germanica L. (including its variety florentina Dykes) and I. pallida Lam.	
Pansy	Viola tricolor L	In alcoholic beverages only.
Passion flower	Passiflora incarnata L	
Patchouly	Pogostemon cablin Benth. and P. heyneanus Benth.	
Peach leaves	Prunus persica (L.) Batsch	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor.
Pennyroyal, American	Hedeoma pulegioides (L.) Pers	
Pennyroyal, European	Mentha pulegium L	
Pine, dwarf, needles and twigs	Pinus mugo Turra var. pumilio (Haenke) Zenari	
Pine, Scotch, needles and twigs	Pinus sylvestris L	

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Pine, white, bark	<i>Pinus strobus</i> L	In alcoholic beverages only.
Pine, white oil	<i>Pinus palustris</i> Mill., and other <i>Pinus</i> spp	
Poplar buds	<i>Populus balsamifera</i> L. (P. tacamahacca Mill.), <i>P. candicans</i> Ait., or <i>P. nigra</i> L.....	Do.
Quassia	<i>Picrasma excelsa</i> (Sw.) Planch, or <i>Quassia amara</i> L.	
Quebracho bark	<i>Aspidosperma quebracho-blanco</i> Schlecht, or (<i>Quebrachia lorentzii</i> (Griseb)).....	<i>Schinopsis lorentzii</i> (Griseb.) Engl.
Quillaia (soapbark)	<i>Quillaia saponaria</i> Mol	
Red saunders (red sandalwood)	<i>Pterocarpus san alinus</i> L	In alcoholic beverages only.
Rhatany root	<i>Krameria triandra</i> Ruiz et Pav. or <i>K. argentea</i> Mart.	
Rhubarb, garden root	<i>Rheum rhaponticum</i> L	Do.
Rhubarb root	<i>Rheum officinale</i> Baill., <i>R. palmatum</i> L., or other spp. (excepting <i>R. rhaponticum</i> L.) or hybrids of <i>Rheum</i> grown in China.	
Roselle	<i>Hibiscus sabdariffa</i> L	Do.
Rosin (colophony)	<i>Pinus palustris</i> Mill., and other <i>Pinus</i> spp	Do.
St. Johnswort leaves, flowers, and caulis....	<i>Hypericum perforatum</i> L	Hypericin-free alcohol distillate form only; in alcoholic beverages only.
Sandalwood, white (yellow, or East Indian).....	<i>Santalum album</i> L	
Sandarac	<i>Tetraclinis articulata</i> (Vahl.), Mast	In alcoholic beverages only.
Sarsaparilla	<i>Smilax aristolochiaefolia</i> Mill., (Mexican sarsaparilla), <i>S. regelii</i> Killip et Morton (Honduras sarsaparilla), <i>S. febrifuga</i> Kunth (Ecuadorian sarsaparilla), or undetermined <i>Smilax</i> spp. (Ecuadorian or Central American sarsaparilla).	

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Sassafras leaves	Sassafras albidum (Nutt.) Nees	Safrole free.
Senna, Alexandria	Cassia acutifolia Delile	
Serpentaria (Virginia snakeroot)	Aristolochia serpentaria L	In alcoholic beverages only.
Simaruba bark	Simaruba amara Aubl	Do.
Snakeroot, Canadian (wild ginger)	Asarum canadense L.	
Spruce needles and twigs	Picea glauca (Moench) Voss or P. mariana (Mill.) BSP.	
Storax (styrax)	Liquidambar orientalis Mill. or L. styraciflua L.	
Tagetes (marigold)	Tagetes patula L., T. erecta L., or T. minuta L. (T. glandulifera Schrank)	As oil only.
Tansy	Tanacetum vulgare L	In alcoholic beverages only; finished alcoholic beverage thujone free. [FN1]
Thistle, blessed (holy thistle)	Onicus benedictus L	In alcoholic beverages only.
Thymus capitatus (Spanish "origanum")	Thymus capitatus Hoffmg. et Link	
Tolu	Myroxylon balsamum (L.) Harms	
Turpentine	Pinus palustris Mill. and other Pinus spp. which yield terpene oils exclusively.	
Valerian rhizome and roots	Valeriana officinalis L	Do.
Veronica	Veronica officinalis L	Do.
Vervain, European	Verbena officinalis L	Do.
Vetiver	Vetiveria zizanioides Stapf	Do.
Violet, Swiss	Viola calcarata L	
Walnut husks (hulls), leaves, and green nuts	Juglans nigra L. or J. regia L	
Woodruff, sweet	Asperula odorata L	In alcoholic beverages only.
Yarrow	Achillea millefolium L	In beverages only; finished beverage thujone free. [FN1]
Yerba santa	Eriodictyon californicum (Hook, et	

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Arn.) Torr

Yucca, Joshua-tree Yucca brevifolia Engelm

Yucca, Mohave Yucca schidigera Roez1 ex Ortgies (Y.
mohavensis Sarg.).

FN1 As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 14644, Apr. 7, 1978; 47 FR 11836, Mar. 19, 1982; 49 FR 10104, March 19, 1984; 54 FR 24897, June 12, 1989]

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< General Materials (GM) - References, Annotations,
or Tables >

END OF DOCUMENT

11/11/1999 12:10

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ORANGE GUARD

PAGE 03

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Organic Materials Review Institute™

Tor McPartland
President
Orange Guard, Inc.
7 Trampa canyon Rd.
Carmel Valley, CA 93824

Dear Mr. McPartland:

Thank you for applying to the Organic Materials Review Institute (OMRI) for brand name product review. OMRI has reviewed Orange Guard, Inc.'s product, Orange Guard, and has determined it is Allowed for use in organic production in the category of plant extract used for processing pest control. This listing indicates that your product meets organic standards based on OMRI's review policy and good faith acceptance of the documentation you provided with your application. OMRI expects to revise its list of materials used in processing and post-harvest handling to be more inclusive, and may reconsider your product at a future date based on that.

Subscribing certifiers and state organic programs will receive information regarding the listing status of Orange Guard with OMRI. The product will appear in the next update of the OMRI Brand Name Products List. This listing is not OMRI certification or endorsement, and cannot be considered as certification or listing by any of the subscribing certifiers. Final decisions regarding the acceptability of use of the product, and any restrictions on its use under any particular certifier program are made by that certifier who still has the right to decline OMRI's recommendation. Producers and handlers still need to contact their certifiers for information as to whether or not this material may be used in organic production or handling. OMRI is not responsible for any issues that may occur as a result of this listing or the actions of OMRI subscribers as the result of this listing.

Also, OMRI listing does not imply that the product has been registered in general or for any particular use by the appropriate state or Federal agencies. Use in organic handling must comply with the current label, and may not be used in direct food contact. Any food contact surface treated with this material must be cleaned before handling organic food. Any revision to label must be provided to OMRI, and may require a reconsideration of the product status.

Enclosed is OMRI's policy on how you can use your listing on labeling and promotional literature. Any use of OMRI's name outside of this sanctioned policy may result in a product being removed from the list or further action against the company that violates that policy. OMRI reserves the right to remove any product from its list at any time. This letter serves as the Final Response Letter to Orange Guard, Inc. regarding the status of Orange Guard. If Orange Guard, Inc. wishes to appeal this decision, please refer to the "Appeals" section of the most current OMRI Operating Manual.

Again, thank you for your participation in the OMRI Materials Review Program. Please let us know if we can be of any further assistance.

Blair Baker, Ph.D.
Technical Director

Exhibit B

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ORANGE GLV

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Minneapolis, MN

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for identification

Wording Options for Suppliers with "Allowed" or "Regulated" Status on the OMRI Brand Name Products List

- OMRI Listed
- Listed by the Organic Materials Review Institute (OMRI) for use in production of organic food and fiber.
- Listed by the Organic Materials Review Institute (OMRI) for use in organic production

To use any or all of these on packaging and in literature, a supplier must be listed as **ALLOWED** or **REGULATED** on the current **OMRI Brand Name Products List**. No other wording options may be used.

Materials listed by OMRI may or may not be registered for use on any or certain crops, animals, or foods for a given State or Federal agency, and OMRI listing does not imply acceptance by any government agency, and it is the user's responsibility to determine the compliance of a particular use of a specific product with all applicable laws and regulations. Contact the appropriate official sources to determine if the use of a given product meets all legal requirements.

OMRI is not a certifier or an enforcement agency, and it does not establish, interpret, or apply certification or legal standards. Decisions about organic certification or legal compliance with organic standards remain the responsibility of the appropriate certifier or enforcement official.

OMRI's recommendations and opinions regarding use of any listed product do not necessarily coincide with applicable governmental or organizational standards. OMRI is not responsible for the loss of certification, loss of organic status, or other consequences for failure to comply with organic legal or certification standards. Producers, processors, and handlers with questions about the acceptability of use or any restrictions on use of a particular material should contact their certifiers or enforcement officials for information.

Organic Materials Review Institute™

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9-19-200 5:47PM

FR: ORANGE GUARD. INC. 831659512P

Tuesday, June 27, 2000

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Preferencos/Netscape%20%C4/Mail/Inbox?Id=

(no subject)

Subject: (no subject)
Date: Sat, 24 Jun 2000 22:11:58 EDT
From: GRadf@aol.com
To: ogi@ix.netcom.com

Just have to thank you for developing this product! Orange Guard is taking care of a terrible ant problem we have. We have five young children and I'm thrilled to have found a "pesticide" I feel comfortable using. You've done a great service. Mary

Exhibit C

9-19-200 5:47PM

FF 1 ORANGE GUARD, INC. 8316595129

Wednesday, August 23, 2000

Thank you for your product

Page: 1

Subject: Thank you for your product
Date: Tue, 22 Aug 2000 01:25:40 EDT
From: MarshNCha@aol.com
To: qgj@ix.netcom.com

We first became acquainted with your product through a demonstration on QVC. We lived in Orange County, CA at that time and our entire county as well as our home was covered with ants. I am asthmatic and can't tolerate any of the bug repellents on the market. To complicate matters we share our home with two dogs and one bird.

What do we have to lose? QVC has a 30 day return policy. We ordered the product and used it. We stayed in the house but the ants left. It was great. We have since moved to Riverside County and they have developed the same ant problem.

A rush call was made to QVC. We received the product today and sprayed our outside door and entry hall. The ants died. I had no problems.

Thank you so much for a great product. Your have saved my life.

Charlotte Friedenbergl, Marcia Baldwin, Zorro, Sasha and Sammy-bird.

9-19-200 5:47PM

FF ORANGE GUARD. INC. 831659512

Page: 1

Friday, April 28, 2000

Great product!

Subject: Great product!**Date: Fri, 28 Apr 2000 09:20:57 -0400****From: Doris Bitler <dbitler@gmu.edu>****To: ogi@ix.netcom.com**

I wanted to let you know how happy I am with Orange Guard. We were having a terrible ant problem, and they seemed to actually like the baits we were putting out. We worried about our dogs and cat getting into the baits, and didn't want to use a spray around them (or us). I found Orange Guard on the web and called you to order some. My husband was doubtful about the effectiveness of a spray that could be used around pets, children and food, but we thought it was worth a try. After just one treatment, the ants are entirely gone. We'll continue using Orange Guard to keep them away. I've never felt the need to write to a company before now, but you have such a great product! It's effective and safe - a winning combination. Thanks!

Doris Bitler
Bethesda, MD

9-19-200 5:48PM

FR ! ORANGE GUARD. INC. 8316595120

**MITCHUM CONSTRUCTION
& ENGINEERING CO., INC.**4917 Emerald Bay Drive
NORTHPORT, ALABAMA 35476

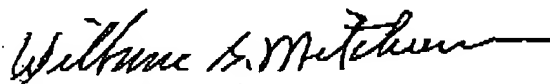
May 25, 1999

Tom McPartland
7 Trampa Canyon Road
Carmel Valley, Ca. 93924

Dear Mr. McPartland:

I want to thank you for sending us a spray bottle of your Orange Guard. After 35 years of ants in my house and being unable to use any other poison due to health problems of my wife I sprayed in several spots as the ants appeared. It now appears that this house is completely ant free. You have a marvelous product for anyone who must destroy ants inside the house. I highly recommend your product.

Sincerely.



Wilburn G. Mitchum

205-339-9595